APR 0 4 2014

510(k) Summary
for the TeleEMG, LLC
CloudEKG

(per 21 CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SUBMITTER/510(K) HOLDER

TeleEMG, LLC
65 Arlington Road
Woburn, MA 01801, USA

Contact Person:
Barry V. Ashar,
Makromed, Inc.
Telephone: (603) 890-3311
Date Prepared: February 24, 2014

2. DEVICE NAME

Proprietary Name: CloudEKG
Common/Usual Name: Wireless electrocardiograph
Classification Name: Transmitters and receivers, electrocardiograph, telephone
Product Code: DXH

3. PREDICATE DEVICES

Corscience BT3/6, BT12, K082077

4. DEVICE DESCRIPTION

Physical Description

CloudEKG is a compact and mobile digital electrocardiograph system. When in connection wirelessly with a receiving unit, the device can be worn on a patient's body and serves as a stand alone EKG system for the following purposes:

- Acquiring EKG signals
- Displaying, processing and storing EKG signals on the receiving unit with the included POLY-SPECTRUM.NET software
- Cardiac monitoring and medical diagnosis support for qualified health care providers

The CloudEKG device is not intended for monitoring critical patients or for intra-cardiac use but can be used in outpatient clinical or doctor practice areas.

The device can also be operated by a properly trained patient for home monitoring purposes. The acquired EKG signals are transferred to an external receiving unit via a Bluetooth interface. The signals can be displayed, saved, read, printed and processed by a trained health care provider and transmitted remotely for further use.

The delivery set includes an electronic unit, a patient cable, 2 AA batteries, a Bluetooth adapter, software, and a user manual.

Depending on the chosen number of leads/standards for recording electrocardiographic signals, recordings can be made from:

1. Four (4) standard leads (Einthoven and Goldberger)
2. Six (6) standard leads (Wilson setup)

Sensors, button and tab electrodes can be connected to ColudEKG via electrode clips on the ECG cables. With the integrated data transmission technology, EKG data can be transmitted online to a nearby PC or handheld device unit for evaluation.

How the Device Functions

The device's principle of operation is based on the recording and transmission of electrocardiogram (EKG) signals to a PC or handheld device for the purpose of cardiac monitoring and diagnosis. The functional scheme of the device is represented in figure 5-1.

The ECG signals collected from the patient are transferred to 8 amplifier channels via the electrodes and cables. The amplified signals are then delivered to multi-channel analog-to-digital converter (ADC).

The ADC processes the received information and transfers it to PC or handheld device via Bluetooth radio interface. The signals are processed with the POLY-SECTRUM.NET software, displayed and presented in different modes. The data can be stored, or processed to generate exam reports, or printed for qualified health care providers to interpret the result.

The required power supply for all electronic components of recording is provided by 2 AA alkaline batteries or rechargeable batteries.

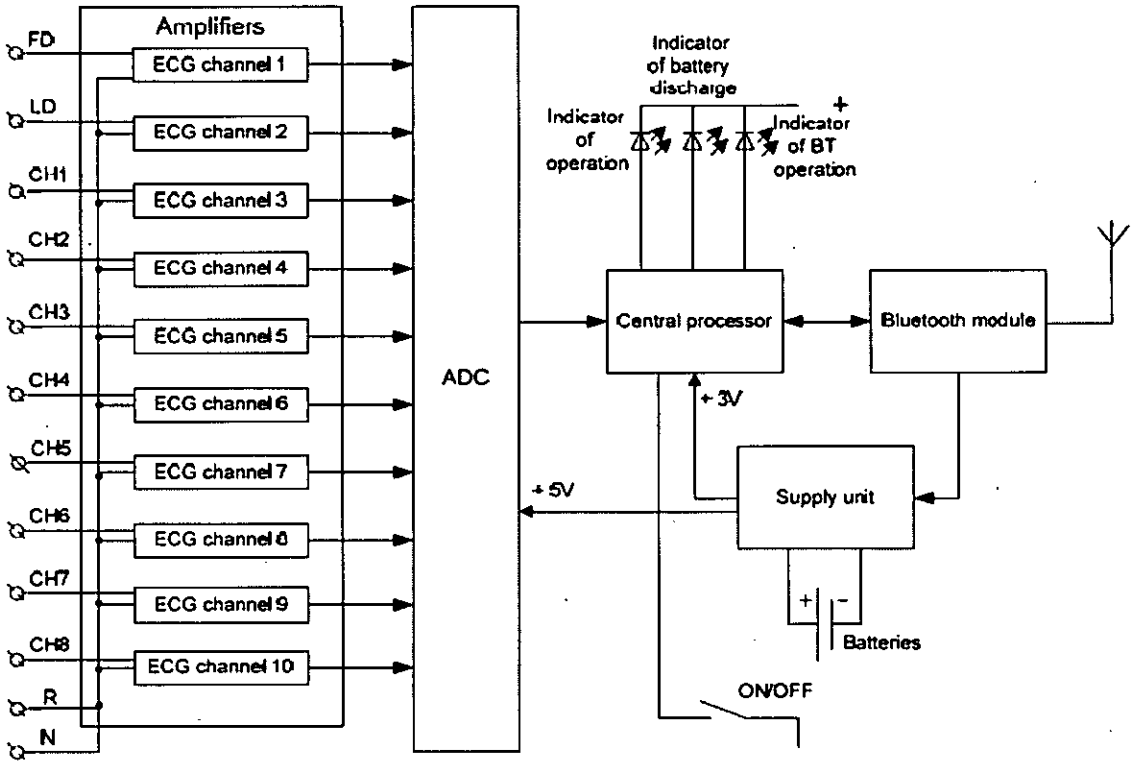


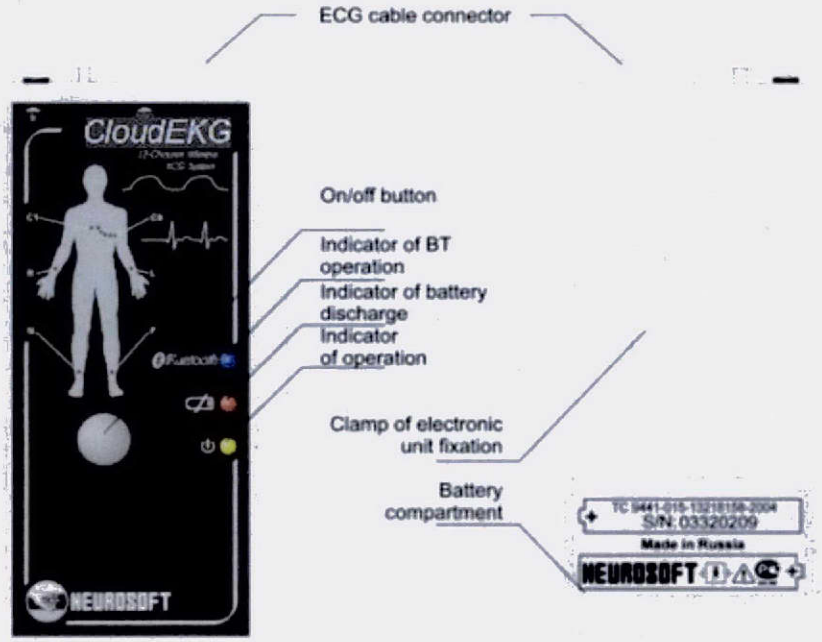
Figure 5-1. Device Functional Scheme

Scientific Concepts that form the Basis for the Device

Electrocardiography (ECG or EKG from the German Elektrokardiogramm) is a noninvasive technique for recording and evaluating electrical activity in the heart. EKG is performed using an instrument called an electrocardiograph, to produce a record called an electrocardiogram generated by the heart muscle cell depolarization during each heartbeat.
The EKG signals can be used to identify if the heart muscle or neural tissues have been damaged and/or to measure the effects of drugs or devices used to regulate the heart, such as a pacemaker.

Significant Physical and Performance Characteristics of the Device, such as Device Design, Material Used, and Physical Properties

The CloudEKG delivery set consists of an electronic unit, a patient cable, 2 AA batteries, a Bluetooth adapter, software and a user manual.



CloudEKG electronic unit (140 × 70 × 24mm)

Patient cable

5. INTENDED USE

The CloudEKG device is a 12 standard leads battery operated unit intended for recording and transmitting standard electrocardiogram signals for cardiac monitoring and diagnosis by healthcare professionals.

Recorded signals are processed by the device and transmitted to a PC or hand-held monitoring device wirelessly using Bluetooth technology.

The transmitted signals are displayed on the monitoring device to allow for their review, analysis, saving, and printing by healthcare professionals.

CloudEKG can be used in adults and infants weighing less than 22 lbs (10 Kg) but is not appropriate for use to monitor critical patients or perform intracardiac recordings.

All measurements obtained with the CloudEKG device should take into account the patient's clinical symptoms and findings to be considered valid and no treatment by drugs or other therapies should be initiated based solely on the measurements obtained with the device.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

Table 5-1. Side-by-Side Comparison of the Proposed Device with Cited Predicate Device

Parameter	CloudEKG	Predicate Device Corscience BT3/6, BT12
Intended use	The CloudEKG device is a 12 standard leads battery operated unit intended for recording and transmitting standard electrocardiogram signals for cardiac monitoring and diagnosis by healthcare professionals. Recorded signals are processed by the device and transmitted to a PC or hand-held monitoring device wirelessly using Bluetooth technology. The transmitted signals are displayed on the monitoring device to allow for their review, analysis, saving, and printing by healthcare professionals. CloudEKG can be used in adults and infants weighing less than 22 lbs (10 Kg) but is not appropriate for use to monitor critical patients or perform intracardiac recordings. All measurements obtained with the CloudEKG device should take into account the patient's clinical	The BT3/6 (3/6-lead) and BT12 (12-lead), hereafter referred to as the "BT devices", are battery powered devices capable of acquiring and transmitting a standard electrocardiogram (EKG) to be applied by medically trained persons for the purpose of cardiac monitoring and diagnosis performed by medical professionals. The collected data is not interpreted by the BT device as this is done by the monitoring device operated by medical professionals. The collected data is processed by the BT device and then transmitted via a standard wireless link to a monitoring device, such as a PC or hand-held device for display, review, printing, saving and post event processing by medical professionals. Use of the BT devices is not restricted to adult population, but is also intended for infants weighing less than 10 kg (22 lbs.). Measurements taken by the BT devices are only significant if considered in connection with other clinical findings.

Parameter	CloudEKG	Predicate Device Corscience BT3/6, BT12
	symptoms and findings to be considered valid and no treatment by drugs or other therapies should be initiated based solely on the measurements obtained with the device.	No therapy or drugs can be administered based solely on ECG data derived from the BT devices. BT devices are not intended for monitoring critical patients and are not intended for intracardiac use.
Compatible ECG electrodes	Any ECG electrodes legally marketed in the U.S.	Only use bio-compatible and CE-approved ECG electrodes with the ECG measuring unit
ECG data processing software	Heart rate and QRS axis calculation. No ECG interpretation for Poly-Spectrum.net software	Heart rate and QRS axis calculation. No ECG interpretation for VM300 software
Input dynamic range	+/- 10 mV	+/- 5 mV
Frequency response bandwidth	0.05-150 Hz	0.05-150 Hz / according to EC11 and IEC 60601-2-51
Resolution	24 bit A/D converter	24 bit A/D converter (15 bit transmitted) 2.58 µV/bit
Leads	3/6 or 12	3/6 or 12
CMRR	100 dB	>94 dB
Pacemaker detection	Yes	Yes
Current consumption	Operation: Not more than 140 mA Stand-by: Not more than 40 mA	For BT12: Operation (incl. transmission): 148 mA Stand-by: 37 mA
Battery type	2 Batteries of AA type	2 × 1.5V alkaline or 2 × 1.2V rechargeable
Input impedance	≥ 20 MΩ	20 MΩ
DC offset correction	± (300 ± 30) mV	± 190 mA
ECG storage capacity	No	5 min/12 channel when transmission is interrupted
Temperature range	Operation: 10-35°C Storage: 5-40°C	Operation: 0-50°C Storage: -20-70°C
Display	No	LCD
Weight	Electronic unit: 200 g incl. batteries	260 g incl. batteries and cable 154 g without batteries, incl. cable
Electronic unit Dimension in mm	140 × 70 × 24	61 × 106 × 23
A to D sampling rate	User–defined, 250, 500 and 1000 Hz	500 samples/sec
Data transmission	Bluetooth radio channel	Wireless (Bluetooth in their product Brochure)
Degree of protection against penetration of water	IPX0	IPX3
Classification	BF	BF
Defibrillation protection	The electronic unit conforms to IEC 60601-1 standard requirements of defibrillator impulse protection.	Device itself is not defibrillation proof, but ECG patient cable supplied with device by manufacturer has

Parameter	CloudEKG	Predicate Device Corscience BT3/6, BT12
	Patient cable includes defibrillation protection circuit.	defibrillation protection circuit. Note in manual that guarantee of defibrillation protection can be given only in combination with original cable.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Performance Testing

Performance evaluation of the features described in the CloudEKG user manual has been successfully completed utilizing hardware and software tests and validations. Hardware qualification is performed using the following industry standards:

- IEC60601-1:1988+A1:1991+A2:1995 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility requirements and tests
- IEC 60601-2-25:1993+A1:1999 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- IEC 60601-2-51: 2003 Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs

The CloudEKG device software was tested as described in section 16 "Software" following the corresponding FDA software guidelines.

Biocompatibility Testing

TeleEMG does not provide electrodes in the delivery set of CloudEKG. Therefore, this testing is not applicable.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted to support this submission.

9. SUMMARY OF OTHER INFORMATION

No other information is available.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information and supporting documentation provided in the premarket notification, the CloudEKG device is substantially equivalent to the cited predicate device. Testing demonstrates that the CloudEKG device fulfills prospectively defined design and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 4, 2014

TeleEMG, LLC
c/o Barry V. Ashar
Makromed, Inc.
88 Stiles Road
Salem, New Hampshire 03079 US

Re: K130878
Trade/Device Name: CloudEKG
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: March 6, 2014
Received: March 7, 2014

Dear Mr. Barry Ashar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (K130878):

Device Name: CloudEKG

Indications for Use:

The CloudEKG device is a 12 standard leads battery operated unit intended for recording and transmitting standard electrocardiogram signals for cardiac monitoring and diagnosis by healthcare professionals.

Recorded signals are processed by the device and transmitted to a PC or hand-held monitoring device wirelessly using Bluetooth technology.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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